# PLANEAIRE HANDS HAND SANITIZER- ethyl alcohol gel EverywhereAire LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# PlaneAire Hands gel Tangerine Coriander hand sanitizer

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol
- c. Water
- d. Other inactive ingredients

# Active Ingredient(s)

Alcohol 70% v/v.

# **Purpose**

Antiseptic

### Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

# Warnings

For external use only on hands. Flammable. Keep away from heat or flame

### Do not use

• on open wounds or near eyes. In case of contact with eyes, rinse thoroughly with water.

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use if irritation or rash develops. If condition persists for more than 72 hours, consult a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a local Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. If condtion persists for more than 72 hours, consult a doictor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- Wet hands thoroughly with product, rub hands, and allow to dry without wiping
- For children under 6 years of age, use only under adult supervision to avoid swallowing
- not recommended for infants

### Other information

- Store between 15-30C (59-86F)
- do not store above 105F
- Avoid freezing
- may discolor some fabrics
- may be harmful to some wood finishes and plastics

# **Inactive ingredients**

aloe vera inner leaf, green tea extract, glycerin, carbomer, tangerine oil, coriander oil, sodium hydroxide, water

# Package Label - Principal Display Panel

# 99.99% OF MOST COMMON GERMS

# **Antiseptic**

Made With Aloe Vera and Green Tea Extract

LIVELY TANGERINE CORIANDER SCENT

2 FL. OZ (60mL)

60 mL NDC: 80335-108-02

# **Drug Facts**

# Active Ingredient

Purpose

Ethyl Alcohol 70% v/v..... Antiseptic

**Uses** ■ helps reduce bacteria that potentially can cause disease for use when soap and water are not available.

### Warnings

For external use only-on hands.

Flammable. Keep away from heat and flame.

Do not use on open wounds or near eyes. In case of contact with eyes, rinse thoroughly with water.

Discontinue use if ■ irritation or redness develops. ■ If condition persists for more than 72 hours, consult a doctor.

Keep out of reach of children. ■ If swallowed, get medical help or contact a local Poison Control Center right away.

### **Directions**

■ Wet hands thoroughly with product, rub hands, and allow to dry without wiping. ■ For children under 6 years of age, use only under adult supervision to avoid swallowing. ■ not recommended for infants

### Other Information

- store between 15-30°C (59-86°F). ■do not store above 105°F ■ avoid freezing ■ may discolor some fabrics
- may be harmful to some wood finishes and plastics

# Inactive Ingredients

Aloe Vera (Inner Leaf), Carbomer, Glycerin, Green Tea Extract (Camellia Sinensis Leaf), Sodium Hydroxide, Tangerine Coriander Oil Blend (Citrus Reticulata and Coriandrum Sativum Oils), Water (Aqua)



Manufactured for EverywhereAire LLC, Princeton, NJ

# Made in the USA

PlaneAire.com 1-800-572-5805

# PLANEAIRE HANDS HAND SANITIZER

ethyl alcohol gel

**HUMAN OTC DRUG** NDC:80335-108 **Product Type** Item Code (Source)

**Route of Administration TOPICAL** 

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
CARBOMER 980 (UNII: 4Q93RCW27E)				
GLYCERIN (UNII: PDC6A3C0OX)				
TANGERINE (UNII: KH3E3096OO)				
CORIANDER OIL (UNII: 7626GC95E5)				
ALOE VERA LEAF POLYSACCHARIDES (UNII: W210437517)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
WATER (UNII: 059QF0KO0R)				

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:80335- 108-02	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/21/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	12/21/2020		

# **Labeler -** EverywhereAire LLC (117635273)

# Registrant - EverywhereAire LLC (117635273)

Revised: 10/2021 EverywhereAire LLC